



# UNITED STATES PATENT AND TRADEMARK OFFICE

7a  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,582	01/18/2002	Glen A. Evans	66663-025	7340

27777 7590 06/29/2005

PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/052,582

Applicant(s)

EVANS, GLEN A.

Examiner

Carolyn L. Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-27 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 15-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14 and 38 is/are rejected.
- 7) ☒ Claim(s) 3 and 38 is/are objected to.
- 8) ☒ Claim(s) 1-5, 7-27 and 38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 72202, 91503.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-14 and 38), filed 10/12/04 and 4/15/05, is acknowledged. Cancelled claims 6, 28-37, and 39-52 are acknowledged. Claims 15-27 are withdrawn from consideration as being drawn to non-elected Groups.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a computer-directed assembly of a polynucleotide encoding a target polypeptide, whereas in contrast the elected claims are specifically directed to a method of synthesizing a target polynucleotide.

The information disclosure statements (IDSs) submitted on 7/22/02 and 8/15/03 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claims herein under examination are 1-5, 7-14, and 38.

### ***Drawings***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, Figures 5 and 13. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks a paper copy, computer readable form, or CD-

Art Unit: 1631

ROM and SEQ ID Nos cited along with each sequence in the Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicant(s) are required to submit a computer readable form sequence listing, and a paper copy, or CD-ROM incorporated by reference into the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

### *Claim Objections*

Claim 38 is objected to due to the inclusion of subject matter which has been non-elected due to a restriction requirement and therefore withdrawn from consideration. The non-elected subject matter includes withdrawn claims 15 and 27.

Claim 3 is objected to because of the following minor informality: Claim 3 fails to end in a period. Appropriate correction is requested.

### *Claims Rejected Under 35 U.S.C. § 112, Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

Claims 1-5, 7-14, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (line 35) and 14 (line 57) recite the phrase “the mixture” which lacks clear antecedent basis as there is no previous mention of this phrase. Clarification of this issue via clearer claim wording is requested. Claims 2-5, 7-13, and 38 are also rejected due to their direct or indirect dependency from claims 1 and 14.

Claim 2 (lines 1-2) recites the phrase “the target polynucleotide” which lacks clear antecedent basis as it is unclear if the phrase is referring to the target in step a) or the last line of instant claim 1. It is noted that these two targets are not necessarily identical. Clarification of this issue via clearer claim wording is requested. Claims 3-4 are also rejected due to their direct or indirect dependency from claim 2.

Claims 5 (lines 1-2) and 13 (lines 1-2) recite the phrase “the initiating polynucleotide” which lacks clear antecedent basis as it is unclear if it is referring to the initiating polynucleotide from steps b), e), or g) of instant claim 1. Clarification of this issue via clearer claim wording is requested.

Claim 14 (line 3) recites the phrase “derived from” which is vague and indefinite. It is unclear what criteria and to what degree these criteria must be met to be considered to be “derived from”. Clarification of this issue via clearer claim wording is requested. Claim 38 is also rejected due to its dependency from claim 14.

Claim 14 (lines 24, 26-27, and 29) recites the phrase “the first plus strand oligonucleotide” which lacks clear antecedent basis as is it unclear if this phrase is referring to

Art Unit: 1631

the oligonucleotide on lines 22-23 or lines 7-8 of instant claim 14. Clarification of this issue via clearer claim wording is requested. Claim 38 is also rejected due to its dependency from claim 14.

Claim 14 (lines 28 and 29-30) recites the phrase “the second plus strand oligonucleotide” which lacks clear antecedent basis as is it unclear if this phrase is referring to the oligonucleotide on line 23 or line 8 of instant claim 14. Clarification of this issue via clearer claim wording is requested. Claim 38 is also rejected due to its dependency from claim 14.

Claim 14 (lines 39, 41-42, and 44) recites the phrase “the first plus strand oligonucleotide” which lacks clear antecedent basis as is it unclear if this phrase is referring to the oligonucleotide on lines 7-8, 22-23, or 37-38 of instant claim 14. Clarification of this issue via clearer claim wording is requested. Claim 38 is also rejected due to its dependency from claim 14.

Claim 14 (lines 43 and 44-45) recites the phrase “the second plus strand oligonucleotide” which lacks clear antecedent basis as is it unclear if this phrase is referring to the oligonucleotide on lines 8, 23 or 38 of instant claim 14. Clarification of this issue via clearer claim wording is requested. Claim 38 is also rejected due to its dependency from claim 14.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1631

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7-13, and 38 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Chesnut et al. (US 2003/0186233 A1).

Chesnut et al. disclose providing a gene target sequence (paragraphs 0024, 0052, 0069, 0086), as stated in step a) of instant claim 1. Chesnut et al. disclose generating a covalently linked recombinant nucleic acid molecule by contacting two or more (including 3) nucleic acid molecules which may be double stranded (ds) (paragraph 0053) which represents annealing an initiating, second, and third polynucleotide, as stated in step e) of instant claim 1. Chesnut et al. disclose the first nucleic acid may have either a 5' or 3' overhang (paragraph 0043) as stated in step b) of instant claim 1. Chesnut et al. disclose that the second nucleic acid molecule has sequence complementarity to at least one end of the first nucleic acid molecule (paragraph 0045) as stated in step c) of instant claim 1. Chesnut et al. disclose using a first (initiating), second and one or more additional ds molecules covalently linked in a predetermined directional orientation (paragraph 0068) which represents the annealing of the three polynucleotides in instant claim 1. Chesnut et al. disclose the possible 5' and/or 3' complementary overhanging sequences that can be used to link the nucleic acids (paragraphs 0274 and 0275). Chesnut et al. disclose linking two or more nucleotides in a particular order (paragraph 0295). Chesnut et al. disclose covalently linking two coding sequences such that they can be transcribed and translated in frame to produce a fusion polypeptide (paragraph 0295), as stated in instant claims 2 and 3. Chesnut et al. disclose identifying sequences (paragraphs 0117, 0205, 0206, 0285, 0454). Chesnut et al.

Art Unit: 1631

disclose contiguous groups within the reference sequence (paragraph 0039). Chesnut et al. disclose complementary annealing of synthetic oligonucleotides (paragraphs 0362 and 0489). Figure 8B demonstrates an initiating sequence with 3' and 5' overhangs, two element sequences with 5' or 3' overhangs and annealing of these sequences. Chesnut et al. disclose the nucleic acid molecules are joined under conditions for annealing (paragraphs 0057 and 0094). Chesnut et al. disclose that the strands may be 5-100 or the like nucleotides in length (paragraph 0081) which represents about 15, 20, 25 nucleotides, as stated in instant claims 7-12. Chesnut et al. disclose using computer programs to determine percent identity of a segment to a given reference molecule (paragraph 0040), as stated in instant claim 5. Chesnut et al. disclose the nucleic acid segments being attached to a solid support (paragraph 0038), as stated in instant claim 13. Chesnut et al. disclose using an automated DNA synthesizer (paragraphs 0452 and 0744).

Thus, Chesnut et al. anticipate the limitations in claims 1-3, 5, 7-13, and 38.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.



Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 21, 2005

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
6/23/05